Reviewer’s report

Title: Legal medicine implications in fibrinolytic therapy of acute ischemic stroke

Version: 1 Date: 30 May 2019

Reviewer: Paolo Fais

Reviewer's report:

Please indicate clearly, maybe at the end of the background paragraph, the aim of this study.

ABSTRACT

Line 18-20

"Conclusion: Obtaining informed consent is a mandatory procedure, which takes time, to the detriment of application of fibrinolytic treatment and therefore, we propose to simplify or even drop the consent, considering that acute stroke represents a major medical emergency"

After saying "Obtaining informed consent is a mandatory procedure" you suggest to "drop the consent". Instead of making proposals, which of course could not be based on a small case series, maybe would be better to report an apparent unfavourable risk-benefit ratio between a complete shared decision making process and a proper therapy. It may indicate a expedited shared decision making process in selected cases to achieve a timely fibrinolytic treatment. I suggest a rephrasing being more cautious, maybe more studies are necessary to recommend "to drop" the consent for this kind of therapy which of course may lead to serious haemorrhagic complications even when properly and timely administered.

BACKGROUND

Line 37 typewriting error "10 ut" is "10 out"

Line 67 "(of which the most well known are attributed to Professor Wardlaw)". Is it necessary to specify this attribution?

Assuming that you say "The protocol used for the application of the treatment is extremely clear, in concordance with the European and local guidelines, furthermore being updated few times" do you think it is necessary to explain in detail the Romanian protocol to treat CVA? Maybe would be more interesting to specify and discuss the differences between the Romanian protocol and
the European guidelines. What are the differences? Why do they differ? Are differences based on social reasons, economic reasons or what?

Line 145-8
I can't understand what do you mean…

In Romania legal medicine issues were yet present before the advent of fibrinolytic therapy (not treaty, tpw error!)?

Please explain better what do you mean

Line 149-51
"At Oradea Emergency County Hospital since March 2012 when this type of treatment was started, fibrinolysis was used in 200 cases of acute CVA. This accounts for approximately 3% of the total acute CVA cases".

Is it the 3% of the total acute CVA cases in line with the wester countries? If no explain or almost hypothesize why.

Please use "imaging" instead of "imagistic" along the text

Line 353-6:
"It is more common to have a complaint filed in situations of omission because, legally, an action that was unsuccessful but which was done for the benefit of the patient is less contentious than the lack of action which passively consumes the patient's possible chances for recovery".

Please specify that this statement could be suitable for this specific setting (i.e. therapy of cerebrovascular accidents) but not for many other medical settings.

Line 273-4
"the discussion will be focused on the interpretations of these documents through the angle of forensic training and practical application"

I can't understand which documents will be considered and interpreted in the discussion…
I think physicians encounter occasional issues in applying fibrinolytic therapy. This sentence seems misleading, please rephrase.

Your casuistry lead to hypothesize Romanian doctors lack of shared decision making skills. It seems there is and insufficient or a inadequate communication between patients/their relatives and medical doctors. Please discuss this possible explanation and propose a possible solution (for example, proposal of training programmes aimed at implementing the skills in shared decision making, implementation at a national level of information of the general population about therapy of CVA, ecc).

"Prognostic elements are uncertain, especially in the first hours from an acute CVA onset. prognostic elements of certainty can be found in severe cases, in which the main problem revolves around determining the hours until death. For the remaining, neither literature nor statistics gives convincing prognostic elements, especially for the worried relatives, who see an element of hope in the fact that a chance exists for recovery/survival. It is also true that it is difficult to set a clear boundary between an unfavorable evolution, a non corresponding standard of care and a medical mistake. Frequently patients or their relatives project their anger and frustration upon the physician who couldn't assure the healing process. In these situations decision making becomes difficult.

Furthermore, complaints can also have as their mere goal the obtainement of a material benefit, and in this setting, they use every possible method of interpretation from the medical documents or specialist testimony."

This long dissertation it is too generic and seems useless considering the logical frame of this paper.

Please rephrase and revise the English of the following sentence "357 Mistaking in action gives the doctor the possibility to correct himself / herself; but mistaking 358 through passivity, he does not have the same possibility: both his chance (to feel the 359 fulfillment of the duty as satisfied) and the patient are lost."

A more detailed discussion on the reasons leading to the lack of consent to fibrinolytic therapy seems mandatory. Is there any literature on similar issues? Which are the reasons of the refusal to perform the fibrinolytic therapy? What are the possible solutions proposed from the available literature? What are the possible solutions do you propose?

Please revise the English.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Unable to assess

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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